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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,476	06/24/2003	Edwin G. Duffin	P-9797.00	7245

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	**PAPER NUMBER**
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,476	DUFFIN ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 21-28* is/are pending in the application.

4a) Of the above claim(s) *21-25* is/are withdrawn from consideration.

5)☒ Claim(s) *26-28* is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 3 is objected to because of the following informalities: "other contacts" should read "other contact" because only two contacts have been set forth. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how deflectable member "projects from the connector bore" in claims 7 and 8 and "project[s] into the bore" in claim 5 (from which claims 7 and 8 depend). In other words, it is unclear how the member projects both from and into the bore.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sluetz et al. (US Re. 31,990), in view of Doan et al. (US 7,031,774, hereinafter "Doan") and Goldreyer (US 4,365,639, hereinafter "Goldreyer"). Sluetz discloses the essential features of the claimed invention including the following:

7. In regards to claims 1 and 2 Sluetz discloses a system comprising an array of electrodes (68 and 69), an assembly of insulated conductors (65), a lead connector with a linear array of contacts to select an electrode (Fig. 1), a pulse generator with a connector bore (18) wherein at each position of the lead connector, a lead connector contact makes connection with the connector bore contact (16) to make a corresponding one of the electrodes as a connected active electrode because it is in communication with the device electronics, and a means for reversibly locking the connector along multiple positions in the bore (col. 6, line 21, and 25). Sluetz does not disclose that, at each position of the lead connector, a first contact and third contact and corresponding electrode are electrically connected to the pulse generator and a second

contact and corresponding electrode is electrically disconnected from the pulse generator. Doan teaches of providing a sliding electrode selection means wherein at each position of the lead connector, a first contact and third contact and corresponding electrode are electrically connected to the pulse generator and a second contact and corresponding electrode is electrically disconnected from the pulse generator (Figs. 4 and 5) to allow various combinations of electrodes to be in electrical communication with the pulse generator, thusly allowing the location of stimulation to be adjusted after final lead implantation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Sluetz' invention by providing a sliding electrode selection means wherein at each position of the lead connector, a first contact and third contact are electrically connected to the pulse generator and a second contact is electrically disconnected from the pulse generator to provide the predictable result of allowing both the polarity and location of stimulation to be adjusted after final lead implantation. Further, Sluetz does not disclose that the electrodes are distributed circumferentially on the lead body. Goldreyer teaches of providing a system having pacing lead with multiple selectable, circumferentially spaced electrodes (21-24) to sense in a very specific area to determine local effects. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Sluetz's invention with a pacing lead with multiple selectable, circumferentially spaced electrodes to sense in a very specific area to provide the predictable result of determining local effects.

8. In regards to claims 3, 5, 7, and 8, Sluetz's modified invention discloses the essential features of the claimed invention except for a connector bore contact that is longer than the other contact or spacers having surface depressions in which deflectable members rest. Doan teaches a contact that is longer than the other contact (64) to provide the predictable result of a contact that can provide locking on the lead and spacers in which deflectable members (94) rest to provide a fluid seal, and are apart from the array of lead contacts when contacts 56 and 58 are selected. Since the spacers are a flexible polymer, the deflectable members inherently create a depression in the spacers. Alternatively, it is well known in the implantable lead arts to provide leads with flexible insulation that includes surface depressions to create a fluid-tight seal between the lead and connector. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Sluetz's invention by providing a contact that is longer than the other contact to provide the predictable result of a contact that can provide locking on the lead, and leads with flexible spacers that include surface depressions to create a fluid-tight seal between the lead and connector.

9. In regards to claim 9, the means for locking includes an actuated member (27 and col. 6, line 3).

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sluetz in view of Doan and Goldreyer, as applied to claim 1 above, and further in view of Bischoff et al. (US 5,843,141, hereinafter "Bischoff"). Sluetz's modified invention discloses the essential features of the claimed invention except for an insertion tool. Bischoff teaches

of providing a multiple connector lead system with an insertion tool to easily pull the lead into cooperation with the energy applicator and a set of spacers with surface depressions in which deflectable members rest to electrically isolate the electrodes and provide a fixation means for the lead. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Sluetz's modified invention with an insertion tool to provide the predictable results of easily pulling the lead into engagement with the energy applicator.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sluetz in view of Doan and Goldreyer, as applied to claim 5 above, and further in view of Peers-Trevarton (US 4,469,104, hereinafter "Peers-Trevarton"). Sluetz's modified invention discloses the essential features of the claimed invention except for deflectable members that rest in surface depressions on the contacts. Peers-Trevarton teaches of providing a multiple electrode connection device with deflectable members that rest in surface depressions on contacts (140) to ensure a close electrical communication between the two contacts. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Sluetz's modified invention with deflectable members that rest in surface depressions on contacts to provide the predictable results of ensuring a close electrical communication between the two contacts. Please note that the examiner is interpreting the surface depression in which the deflectable member rests is the unlabelled feature in proximity to element 172 in Figure 1.

Allowable Subject Matter

12. Claims 26-28 are allowed.

Response to Arguments

13. Applicant's arguments filed 12/13/2007 have been fully considered but they are not persuasive. Applicant argued that an artisan of ordinary skill would not have been motivated to combine Sluetz and Doan because Doan is not a header connector, but a mobile boot. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both standards apply because lead connectors and header connectors are in the same field of endeavor and both devices apply to the same problem of effectively selecting electrodes after implantation.

14. Applicant further argued that the combined references fail to disclose the features of claim 2 because none of the contacts remain connected to the same lead connector contact upon repositioning of the lead. However, the claim language does not require this feature because there is no language that requires the first, second, and third contacts in a first position of the connector to be the same first, second, and third contacts in a second position of the connector. In other words, contacts 1, 2, and 3 can be reassigned between positions.

15. In regards to the arguments pertaining to the surface depressions, please see the new grounds of rejection, necessitated by amendment.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK
2/16/08

GEORGE R. EVANISKO
PRIMARY EXAMINER
2/17/8